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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

WARE, TODD

ART UNIT PAPER NUMBER

1615

DATE MAILED: 07/03/2002

5

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/786,549

Applicant(s)

PRIEWE ET AL.

Examiner

Todd D Ware

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Receipt of preliminary amendment filed 3-7-01 and information disclosure statement filed 6-7-01 is acknowledged. Claims 3-5 and 11 have been amended as requested. Claims 1-15 are pending.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
3. Recitation of "implants that consist of" and "characterized in that the polymer mixture contains a polycyanoacrylic acid" in claims 1 is indefinite since the claim utilizes language to "close" the claim in combination with language that is open-ended to include additional, unrecited elements the claim. Therefore, the scope of the claim can not be ascertained since it is unclear whether applicant intends not to exclude additional, unrecited elements in the claims. Furthermore, dependent claims recite additional elements not set forth in the independent claim. See MPEP 2111.03 for further clarification. For purposes of examination, the claims are understood to not to exclude additional, unrecited elements in the claims.
4. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since

Art Unit: 1615

the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 8 recites the broad recitation proteins, and the claim also recites albumin, gelatin, fibrinogen, fibrin, hirudin, heparin, collagen, immunoglobulin, and polypeptides which is the narrower statement of the range/limitation. Similarly, claim 10 recites the broad recitation softener, and the claim also recites nonylphenoxypolyethylene oxide, octoxynol, and poloxomer which is the narrower statement of the range/limitation.

5. Claim 10 contains the trademark/trade names Synperonic NP20, Triton X-100, Pluronic F127, and Pluronic F68. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the

Art Unit: 1615

goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe nonylphenoxypolyethylene oxide, octoxynol, and poloxomer and, accordingly, the identification/description is indefinite.

6. Recitation of "at least one other polymer" in claim 5 is indefinite since the claim(s) include(s) elements not actually disclosed (those encompassed by "other"), thereby rendering the scope of the claim(s) unascertainable.

7. Recitation of "special incubation vessel" is indefinite. The claim does not set forth why the vessel is special or the characteristics that set it apart from another vessel.

8. Claims 12 and 15 provides for the use of polymers and a sterile solution, respectively, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim Rejections - 35 USC § 101

9. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

10. Claims 12 and 15 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App.

Art Unit: 1615

1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

12. Claims 1-3, 5, 8, 12-14 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Tam et al (6,287,249; hereafter '249) or Tam et al (6,261,320; hereafter '320).

'249 and '320 both disclose cyanoacrylate polymer coated stents where the stents are coated with the polymer by immersing the stent in a polymer solution. These stents are also coated with a protein such as heparin.

13. Claims 1-5, 8-10, 12-14 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Goldstein et al (6,143,037; hereafter '037).

'037 discloses medical devices such as stents coated with a butyl ester cyanoacrylate polymer where the polymer is applied to the medical device by dipping

Art Unit: 1615

the medical device in a solution of the polymer. '037 also discloses that proteins are applied to the device.

14. Claims 1-2, 4-8, 11-12 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Clark et al (6,143,352; hereafter '352).

'352 discloses medical devices coated with a butyl ester cyanoacrylate polymer where the polymer is applied to the medical device by dipping the medical device in a solution of the polymer. '352 also discloses that proteins and calcium carbonate are applied to the device and that the coating compositions are sterilized.

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

Art Unit: 1615

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

17. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Goldstein et al (6,143,037; hereafter '037) in view of Clark et al (6,143,352; hereafter '352).

'037 teaches medical devices such as stents coated with a butyl ester cyanoacrylate polymer where the polymer is applied to the medical device by dipping the medical device in a solution of the polymer. '037 also discloses that proteins are applied to the device.

'352 teaches medical devices coated with a butyl ester cyanoacrylate polymer where the polymer is applied to the medical device by dipping the medical device in a solution of the polymer. '352 also discloses that proteins and calcium carbonate are applied to the device and that the coating compositions are sterilized.

Accordingly, it would have been obvious to one skilled in the art at the time of the invention to combine '037 and '352 and apply a sterilized coating composition to a stent by dipping the stent into the sterile solution of polymer with the motivation of avoiding infection in the subject treated with the stent.

Conclusion

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Todd D Ware whose telephone number is (703) 305-1700. The examiner can normally be reached on M-F, 8:00 AM - 4:30 PM.

Art Unit: 1615

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703)308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.


THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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June 30, 2002